

DISCUSSION OF THE CLAIMS

Claims 1-25 are pending in the present application. Claim 4 is presently withdrawn from active prosecution. Independent Claims 1 and 5 are amended to limit the amount of chelating agents selected from the group now recited in the claims to 0.1% by weight or less. Support for the amendment is found in the paragraph bridging pages 4 and 5 of the specification. Claim 1 requires the presence of the acid in an amount of 0.17-10 wt%. Support for the amendment is found in the examples. Claims 18-25 are new claims. Support for new Claims 18 and 19 is found in the previously presented claims. Support for new Claims 20 and 21 is found in paragraph [0019] of the PG publication corresponding with the present application, i.e., US 2007/0128131. Support new Claims 22 and 23 is found throughout the specification and examples of the present application. The present application describes a number of embodiments in which compositions include a calcium ion-supplying compound in an amount that is greater than the amount of a corresponding monofluorophosphate ion-supplying compound. Support for new Claims 24 and 25 is found in Table 2.

No new matter is believed to have been added by this amendment.

REMARKS

Applicants request reconsideration in view of the following remarks submitted concurrently with a RCE.

35 U.S.C. 112

The Office rejected the previously presented claims for including subject matter allegedly not described in the as-filed specification. In particular the Office objected to the inclusion of the term “homogeneous” in the previously presented claims. Applicants submit that those of ordinary skill in the art readily recognize that the original specification implicitly and/or inherently describes homogeneous compositions and therefore the inclusion of this term in the claims does not represent new matter. For example, the original specification describes compositions which are in the form of a solution. Applicants submit that those of skill in the art readily recognize that a solution is a homogeneous fluid composition. The examples of the original specification describe mouthwash compositions which are in the form of solutions. See paragraph [0023] of the PG publication which explicitly describes a liquid composition in the form of a mouthwash.

Further, the compositions of the present application are described in a manner which distinguishes them from compositions which result in undesirable precipitation, e.g., the undesirable formation of a non-homogeneous composition.

Applicants thus submit that the inclusion of the term “homogeneous” in the original claims does not represent new matter and respectfully request withdrawal of the rejection.

The amendment to the claims is believed to obviate the rejection for indefiniteness set forth in the June 2, 2010 Office Action. Irrespective of the amendment to the claims, Applicants submit that those of skill in the art readily recognize what the term “substantially” means in the context of the present disclosure. In fact, the paragraph bridging pages 4 and 5

of the specification provides an explicit explanation of what it means to not “substantially add a chelating agent”. Applicants thus submit that the subject matter of new dependent Claims 18 and 19 should not be rejected for indefiniteness.

35 U.S.C. 103

The Office newly rejected the claims submitted with the Amendment of February 23, 2010 as obvious over Forward (US 4,193,988) in combination with Lee (US 6,214,321). Applicants traverse the rejection for the reason, *inter alia*, that the Office provided insufficient reasons why one of ordinary skill in the art would modify Forward in the manner of Lee and/or for the reason that those of skill in the art would have no motivation to combine the respective Forward and Lee disclosures.

The present application describes an invention in which a chelating agent (e.g., citrate) is preferably not substantially added. In this aspect of the invention, *avoiding* the chelating agent prevents the decrease of calcium ion concentration. This in turn allows improved remineralization of teeth (see paragraphs [0012] and [0016] of the PG publication (i.e., US 2007/0128131)).

The Forward patent describes a different composition; namely, a composition in which pH is controlled by *adding* substances such as citric acid (see column 2, lines 62-65 of the Forward patent). Forward does not appreciate and does not disclose the difficulties encountered when sodium monofluorophosphate is used in combination with calcium glycerophosphate and thus does not appreciate the chelate-avoidance aspect of the present invention. Applicants on the other hand disclosed the difficulties associated with using sodium monofluorophosphate in admixture with a calcium ion-supplying compound (see for example paragraphs [0003] and [0011] of the PG publication).

Citric acid in particular binds strongly to calcium ions to thereby chelate the calcium ion and make the calcium unavailable for the purpose of remineralizing teeth. The invention described in the present claims avoids this undesirable function of chelation by requiring that chelating agents such as citrate (e.g., a salt or ester derived from citric acid) are included in an amount of no more than 0.1 wt%. This requirement of the present claims is directly contradictory to the Forward disclosure in which citric acid (e.g., a progenitor of the citrate chelating agent) is added to control pH (see column 4, second paragraph of Forward).

Applicants disclosed a composition which permits the stable supply of calcium ions for the remineralization of teeth by using a particular acid to control the pH to 4-6.2. Forward describes modifying the acidity of compositions with an acid agent (e.g., citrate). In contrast, the present claims restrict the amount of chelating agent (e.g., citrate) to no more than 0.1%.

With respect to the relative amount of the chelating agents which may be present in the claimed composition, Applicants further draw the Office's attention to previously pending Claim 10 which describes a composition having 0.01% by weight or less of the chelating agent.

Applicants submit that the Office's allegation of obviousness is not supportable at least for the reason that the Forward patent fails to disclose or suggest the invention presently disclosed and claimed.

Lee fails to remedy the defects of Forward. It is an explicit requirement of the present claims that the claimed composition is "homogeneous". Lee describes a composition that must be in separate parts (see the Abstract of Lee). Importantly, at least one of the components of the Lee composition must have a pH that is outside of the pH range recited in the present claims (see the Abstract of Lee). Further, even if the separate portions of the Lee composition were combined, the resulting composition would violate the "homogeneous"

requirement of the present claims because hydroxyapatite precipitates (see the Abstract of Lee).

Lee further discloses that citrate chelating agents are useful for sequestering ferric/ferrous ion (see column 5, lines 12-23 of Lee). Contrary to suggesting the exclusion of chelating agents in the manner of the present claims, Lee encourages the inclusion of chelating agents for the purpose of sequestering certain ions.

Those of skill in the art reading Lee in view of Forward would have no reason to believe that the presently claimed homogeneous composition could be derived from a modification of Forward in the manner of Lee.

Applicants respectfully request withdrawal of the rejection.

At least Claims 5, 12, 14, 15, 16, and 17 describe embodiments of this aspect of the invention in terms of resistance to the precipitation of calcium-containing materials. Such properties are directly contradictory to the properties of the Lee compositions, i.e., the generation and deposition of hydroxyapatite. Applicants thus submit that the aforementioned claims are further patentable over the cited art.

New dependent Claims 22-23 describe compositions in which the calcium ion-supplying compound is present in a greater amount than the monofluorophosphate ion-supplying compound. New dependent Claims 22 and 23 are further patentable over the combination of Forward and Lee for the reason that Forward describes compositions in which a calcium-containing material is present in substantially greater amounts than a monofluorophosphate-containing compound, i.e., a composition in which sodium monofluorophosphate and calcium glycerophosphate are present in relative amounts of 10:1 to 3:1. In Lee the sodium monofluorophosphate is present in substantially greater amounts than the calcium glycerophosphate (see the Abstract of Forward). New Claims 24 and 25

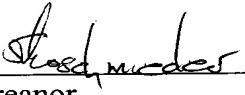
further define the relative amounts of the monofluorophosphate ion-supplying and calcium ion-supplying compounds of the present claims.

Claims 20 and 21 are likewise further patentable over the cited art. Where Forward describes a pH range that is 6 or greater (see column 2, lines 62-65), new dependent Claims 20 and 21 describe pH ranges that do not include a pH of 6. Applicants thus submit that new Claims 20 and 21 are further patentable over the cited art.

For the reasons discussed above in detail, Applicants respectfully request withdrawal of the rejection and the allowance of all now-pending claims.

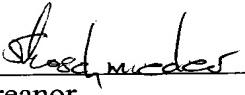
Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, L.L.P.



Richard L. Treanor

Attorney of Record
Registration No. 36,379



Stefan U. Koschmieder, Ph.D.
Registration No. 50,238

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413-2220
(OSMMN 08/09)